

Am. Compl. ¶ 57. These conclusory allegations fail to identify any facts concerning how ZLB Behring¹ “caused” the filing of false claims, nor does it identify the providers who filed such claims with the Medi-Cal program, the dates such claims were filed, or the blood factor drugs at issue in such claims. The allegations thus fall fatally short of the requirement that Plaintiffs plead the “circumstances of fraud” with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure.

In the False Claims Act (“FCA”) context, Rule 9(b) requires not only that the underlying fraudulent scheme be pled with particularity, but also that allegations relating to the actual false claims submitted to the government – which “constitute the essential element of an FCA qui tam action” – be similarly pled. See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 232 (1st Cir. 2004) (affirming dismissal of FCA claims for failure to comply with Rule 9(b)). Conclusory statements that false claims were submitted to the government as a result of fraudulent activity are insufficient to meet this stringent standard. See United States ex. rel. Clausen v. Lab. Corp. of Am., Inc., 290 F.3d 1301, 1311 (11th Cir. 2002) (affirming dismissal of complaint on Rule 9(b) grounds where plaintiff did not identify any dates or amounts of claims and no copy of a single claim or payment was provided). Instead, a plaintiff “must provide details that identify particular false claims for payment that were submitted to the government.” See Karvelas, 360 F.3d at 232-33. Such details should include “the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices.” Id. Although these specifics

¹ ZLB Behring is one of the defendants collectively referred to as “ARMOUR-BEHRING.” See Am. Compl. ¶ 6.

“do not constitute a checklist of mandatory requirements..., some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).” *Id.* at 233 (internal citations omitted).

In this case, Plaintiffs’ allegations against ZLB Behring concerning blood factor drugs fall far short of the requisite degree of particularity required for FCA claims. Under California law, it continues to be the responsibility of the provider – rather than a drug manufacturer such as ZLB – to provide accurate pricing information for blood factor drugs to the Medi-Cal Program. Specifically, providers are required to make the following certification in every claim they submit to Medi-Cal for reimbursement related to blood and blood derivative products:

I certify that my acquisition cost of the anti-hemophilia factor claimed here NDC_____ is ___ cents per unit. As used here, the term “acquisition cost” means invoice cost less all off-invoice discounts and rebates except the standard discount for payment by the tenth of the month.

See Medi-Cal Pharmacy Provider Manual (Apr. 2004), *available at* http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/blood_m01o03o04p00.doc. (attached as Exhibit 1 hereto). Thus, to the extent that any entity filed claims with Medi-Cal which inflated acquisition costs, it would have been the providers, not pharmaceutical companies such as ZLB Behring.

In an attempt to proceed against ZLB Behring notwithstanding this provider-focused certification requirement, Plaintiffs baldly allege that ZLB Behring “caused” the filing of false claims with Medi-Cal. Am. Compl. ¶ 57.² Other than this completely conclusory allegation, however, Plaintiffs’ complaint is utterly devoid of any specific statements describing how ZLB Behring could be liable for claims submitted by providers. For instance, the Amended

² This “caused” language is apparently pertinent to the first, second and fourth counts of Plaintiffs’ Amended Complaint.

Complaint contains no allegations that ZLB Behring instructed or coerced providers to submit false claims to Medi-Cal related to blood factor drugs or otherwise had control over the contents of the provider-submitted certifications made to the state. Given these material omissions, there can be little doubt that this aspect of Plaintiffs' Amended Complaint lacks the specificity required by Rule 9(b), and should therefore be dismissed.

Other aspects of Plaintiffs' claims against ZLB Behring similarly are deficient under Rule 9(b).³ For example, Plaintiffs fail to identify by name anywhere in their complaint or accompanying exhibits a single "blood factor" drug manufactured by ZLB Behring for which ZLB Behring allegedly caused false reimbursement claims to be filed. Plaintiffs also fail to provide the names of any of the providers who filed the allegedly false claims with the state. Moreover, Plaintiffs' allegations regarding ZLB Behring fail to identify with the requisite specificity the time period in which ZLB Behring allegedly "caused" false claims to be submitted to the Medi-Cal Program. Instead, Plaintiffs broadly allege that such claims were submitted over a 12-year period (from January 1, 1994 to the present), the same time period for which Plaintiffs seek to proceed against all other defendants. See Am. Compl. ¶ 56. Plaintiffs' failure to provide such basic factual allegations in their Amended Complaint compromises ZLB Behring's ability to defend against such fraud-based charges, and thereby violates Rule 9(b)'s particularity requirement. See Driscoll v. Landmark Bank for Sav., 758 F. Supp. 48, 52 (D. Mass. 1991) (The first goal of Rule 9(b) is to "place the defendants on notice and enable them to prepare meaningful responses to charges of fraud, thereby protecting them from unfair surprise.") (internal quotation omitted).

³ These deficiencies are pertinent to all counts of Plaintiffs' Amended Complaint.

CONCLUSION

For the foregoing reasons, and those presented in Defendants' Joint Memorandum, Plaintiffs' First Amended Complaint-In-Intervention against ZLB Behring should be dismissed with prejudice.

AVENTIS BEHRING, LLC
By its Attorneys,

/s/ Aimée E. Bierman
Michael DeMarco (BBO #119960)
mdemarco@klng.com
Aimée E. Bierman (BBO #640385)
abierman@klng.com
KIRKPATRICK & LOCKHART
NICHOLSON GRAHAM LLP
75 State Street
Boston, MA 02109
(617) 261-3100

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CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2006, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Aimée E. Bierman

Aimée E. Bierman